

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of : BONNEY, Stanley George *et al.*
Filing No. : 10/523,066
Filing Date : January 24, 2005
Title : MEDICAMENT DISPENSER
Group / Art Unit : 3772
Examiner : PATEL, Nihir B.
Confirmation No. : 7458
Docket No. : PG4884USw

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
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APPEAL BRIEF

Applicants hereby appeal the Final Rejection dated June 27, 2008. This Appeal Brief is in furtherance of the Notice of Appeal filed on August 27, 2008 and is filed together with the fee under 37 CFR §41.20(b)(2). It is respectfully submitted that the instant Appeal Brief is in compliance with 37 CFR §41.37(c).

I. **REAL PARTY IN INTEREST**

The real party in interest is Glaxo Group Limited.

II. **RELATED APPEALS AND INTERFERENCES**

Appellant is unaware of any appeals, interferences, or judicial proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the present Appeal.

III. STATUS OF CLAIMS

Claims 1-13 and 15-23 are pending in the application. Claim 14 has been cancelled. Claims 1-13 and 15-23 have been finally rejected and are the subject of this appeal. No claims have been substantively allowed. The claims on appeal are provided in the attached appendix.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Rejection of June 27, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to a unitary dispensing device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product. The device includes a first medicament dispenser containing the first medicament, at least one further medicament dispenser containing at least one further medicament, and a mixing chamber that includes inlets for receiving medicament from each medicament dispenser and an outlet for delivery of the combination medicament product.

The first medicament dispenser and the at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of delivery. The first medicament dispenser is different in type to the at least one further medicament dispenser. Types of medicament dispensers include, but are not limited to, reservoir dry powder inhalers (RDPI), multi-dose dry powder inhalers (MDPI), unit dose dry powder inhalers (UDPI), metered dose inhalers (MDI) and liquid spray inhalers (LSI).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4, 12-14, 17, and 18 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,923,202 (Riccio). Claim 23 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Riccio. Claims 5-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Riccio in view of U.S. Patent No. 3,704,725 (Marand). Claims 19-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Riccio in view of U.S. Patent No. 5,002,048 (Makiej, Jr.). Claim 16 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Riccio in view of U.S. Patent No. 6,958,691 (Anderson *et al.*).

For the purpose of this appeal and in the interest of judicial economy, Applicants elect to have all claims, claims 1-13 and 15-23, considered in a single group.

Accordingly, Applicants respectfully ask the Board to decide whether claim 1, the sole independent claim, is anticipated by Riccio.

VII. ARGUMENT

As stated in Section VI above, Applicants respectfully ask the Board to decide whether claim 1, the sole independent claim, is anticipated by Riccio.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

To narrow the issue even further, Applicants respectfully ask the Board to decide whether the source of gas under pressure represented by cylinder **18** of Riccio is a first medicament container containing a first medicament as recited in claim 1.

Riccio proposes "a dispensing device having a source of gas under pressure and a source of liquid to be dispensed which is also under pressure" (Riccio, col. 2, lines 23-25). Riccio describes a source of gas under pressure as follows:

A source of gas under pressure in the form of an air compressing piston cylinder means is provided on the opposite end of the body **10** from the measured dose dispenser, and in the embodiment disclosed comprises a cylinder **18** which extends downwardly from the body **10** and within which a piston **19** is slidably positioned.

(Riccio, col. 3, lines 27-32). Riccio describes the operation of the device as follows:

In the operation of the overall device, when pressure is exerted by the fingers of the user on the cylinder **32** of the measured dose dispenser and the piston **19** of the air compressing piston cylinder means, the measured dose dispenser is caused to operate to dispense a squirt of liquid through the hollow stem portion **37** into the product flow path **15** and into the mixing chamber **17**. At the same time, air is compressed in the cylinder **18** ahead of the piston **19**. However, until the piston **19** reaches the end of its stroke, the poppet valve **25** remains closed. When the actuating pin **29** hits the poppet valve **25**, the poppet valve is lifted from the seat **26**, as shown in FIG. 2, and the air compressed in the cylinder **18** is suddenly released to flow through the compressed air path to the mixing chamber **17** around the nozzle insert **14**. The compressed air flowing into the mixing chamber **17** mixes and shears the liquid under pressure from the metered dose dispenser and this mixture flows through the lateral passages **14b** and then out through central outlet passage **14a** of the nozzle insert. Due to this mechanical break action the liquid is immediately dispensed from the nozzle insert as a fine spray of droplets of the liquid in compressed air without there first being ejected relatively large droplets of liquid.

(Riccio, col. 4, line 56 to col. 5, line 11). Riccio describes alternative sources of gas under pressure, stating:

while the piston cylinder air pressurizing means have been described as a specific source of gas under pressure, other sources could be provided, for example, a valved conventional aerosol can containing a conventional propellant under pressure.

(Riccio, col. 5, lines 25-30).

The Examiner asserts that the description of alternative sources of gas under pressure found at column 5, lines 25-30 of Riccio “provide[] an implicit teaching that the cylinder 18 can be used as a first medicament container as recited in claim 1.” (Final Office Action, mailed June 27, 2008). Applicants disagree with the assertions of the Examiner.

Claim 1 recites, *inter alia*, a first medicament dispenser containing a first medicament.

Riccio does not provide a teaching, either explicitly or implicitly, that the cylinder 18 can be used as a first medicament container containing a first medicament as recited in claim 1. It is clear from the passages quoted from Riccio above, as well as a reading of the Riccio reference as a whole, that column 5, lines 25-30 of Riccio merely provide a description of sources of gas under pressure that can be used as alternatives to the compressed air source of gas under pressure described in the embodiments of Riccio. Contrary to the assertions of the Examiner, Riccio’s description of alternative sources of gas under pressure does not provide an implicit teaching that the cylinder 18 can be used as a first medicament container as recited in claim 1.

Riccio does not describe, either expressly or inherently, each and every element as set forth in claim 1. Accordingly, claim 1 is not anticipated by Riccio. As claims 2-13 and 15-23 each depend either directly or indirectly from patentable independent claim 1, these claims are also patentable.

CONCLUSION

Accordingly, the Board is respectfully requested to reverse the final rejections and remand this application for issuance.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

Claim 1 (Previously Presented): A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product, the device comprising

a first medicament dispenser containing said first medicament;

at least one further medicament dispenser containing said at least one further medicament, and

a mixing chamber comprising inlets for receiving medicament from each medicament dispenser and an outlet for delivery of the combination medicament product,

wherein said first medicament dispenser and said at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of delivery, and the first medicament dispenser is different in type to the at least one further medicament dispenser.

Claim 2 (Original): A medicament dispenser device according to claim 1, wherein the device comprises the first medicament dispenser and only one further medicament dispenser.

Claim 3 (Previously Presented): A medicament dispenser device according to claim 1, wherein the first medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) and the at least one further medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI).

Claim 4 (Previously Presented): A medicament dispenser device according to claim 1, wherein, the first medicament dispenser is a reservoir dry powder inhaler (RDPI), and the at least one further medicament dispenser is of a type selected from the group consisting of a multi-dose dry powder inhaler (MDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI).

Claim 5 (Previously Presented): A medicament dispenser device according to claim 1 wherein the first medicament dispenser is a multi-dose dry powder inhaler (MDPI), and the at least one further medicament dispenser is of a type selected from the group consisting of a reservoir dry powder inhaler (RDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI).

Claim 6 (Previously Presented): A medicament dispenser device according to claim 1 wherein the first medicament dispenser is a metered dose inhaler (MDI), and the at least one further medicament dispenser is of a type selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI) and a liquid spray inhaler (LSI).

Claim 7 (Previously Presented): A medicament dispenser device according to claim 1 wherein the first medicament dispenser is a liquid spray inhaler (LSI), and the at least one further medicament dispenser is of a type selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI) and a metered dose inhaler (MDI).

Claim 8 (Previously Presented): A medicament dispenser device according to claim 3, wherein the multi-dose dry powder inhaler (MDPI) is arranged to reversibly receive a multi-dose blister pack suitable for containing medicament in dry powder form.

Claim 9 (Original): A medicament dispenser device according to claim 8, wherein the multi-dose blister pack comprises plural blisters arranged sequentially along an elongate strip.

Claim 10 (Original): A medicament dispenser device according to claim 9, wherein the strip form multi-dose blister pack comprises an elongate base sheet having plural blister pockets defined therein; and secured thereto and elongate lid sheet, wherein said elongate base sheet and lid sheet are peelably separable to enable access to said blister pockets.

Claim 11 (Previously Presented): A medicament dispenser device according to claim 3, wherein the metered dose inhaler (MDI) is arranged to reversibly receive an aerosol canister suitable for containing medicament in dry powder form.

Claim 12 (Previously Presented): A medicament dispenser device according to claim 3, wherein the metered dose inhaler (MDI) is arranged to reversibly receive a liquid container suitable for containing medicament in liquid form.

Claim 13 (Previously Presented): A medicament dispenser device according to claim 1, additionally comprising a coupled actuator for the first medicament dispenser and the at least one further medicament dispenser.

Claim 14 (Cancelled).

Claim 15 (Previously Presented): A medicament dispenser device according to claim 1, wherein said outlet communicates with a common mouthpiece.

Claim 16 (Previously Presented): A medicament dispenser device according to claim 1, additionally comprising a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to said breath sensor.

Claim 17 (Previously Presented): A medicament dispenser device according to claim 1, wherein the first medicament dispenser includes a medicament container for containing the first medicament and the at least one further medicament dispenser includes at least one further medicament container for containing the at least one further medicament.

Claim 18 (Original): A medicament dispenser device according to claim 17, wherein the first medicament container contains the first medicament and the at least one further medicament container contains at least one further medicament.

Claim 19 (Original): A medicament dispenser device according to claim 18, wherein the first medicament comprises a bronchodilator and the at least one further medicament comprises an anti-inflammatory.

Claim 20 (Original): A medicament dispenser device according to claim 19, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a steroid.

Claim 21 (Original): A medicament dispenser device according to claim 20, wherein said bronchodilator is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts or solvates thereof and mixtures thereof.

Claim 22 (Previously Presented): A medicament dispenser device according to claim 20, wherein said anti-inflammatory is selected from the group consisting of a beclomethasone ester, fluticasone ester, budesonide and any salt or solvates thereof and mixtures thereof.

Claim 23 (Previously Presented): A method of delivering a combination medicament product comprising the steps of

- a.) providing a patient in need thereof a medicament dispenser device according to claim 1 and
- b.) dispensing a combination medicament product from said device.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.